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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,783	10/17/2003	Richard R. Heuser	HEU 309	9851
23581	7590	08/24/2004	EXAMINER	
KOLISCH HARTWELL, P.C. 520 S.W. YAMHILL STREET SUITE 200 PORTLAND, OR 97204			JACKSON, SUZETTE JAMIE	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/687,783	Applicant(s) HEUSER, RICHARD R.	
	Examiner Suzette J Jackson	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 17 recites the limitation "*the radiopaque portion of the inner or outer layer..*". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Bynon et al. 5,667,523. Bynon et al. discloses the invention as claimed comprising: A stent (20) with an outer mesh layer with first and second opposing ends (12, 14); an inner mesh layer (18) defining a shape with opposed first and second ends; wherein the inner mesh layer is fitted within the outer mesh layer and the layers have substantially equal lengths; and a film layer with opposing first and second ends and wherein the film is fitted between the inner and outer mesh layers; and wherein the film layer is made from PTFE (col. 7, line 8); wherein the ends of the film layer extend beyond the ends of the mesh layers (see col. 7, lines 47-49).

6. Claims 8-9, 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Golds et al. 2004/0162603. Golds et al. discloses the invention as claimed noting figure 1 comprising: A stent (2) with an inner layer providing a first flexible covering (4); an outer layer providing a second flexible covering (6) and a middle wire mesh layer (2) between the inner and outer layers, the wire mesh layers being self-expandable; wherein the inner and outer layers are PTFE [section 0014].

7. Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Ruiz 6,120,534. Ruiz discloses the invention as claimed noting figures 5c-6 comprising: a stent having a mesh layer a middle portion, proximal and distal ends and a central lumen; and a balloon catheter. The intended use recitation/functional language of the claim carries no patentable weight in the absence of any distinguishing structure.

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These are article claims and Ruiz clearly discloses the structure as claimed and is found to be inherently capable of performing the function.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bynon et al. 5,667,523 Bynon et al. has been disclosed above however Bynon et al. does not specifically state that the length that the film layer extends is at least about 0.5mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the film layer (16) of Bynon et al. and extend the film layer to any length beyond the mesh layers in order to help encase the mesh layers and/or to help protect the blood vessel from the ends of the mesh.

10. Claims 10-11 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golds et al. in view of Chouinard 6,709,455. Gold has been disclosed above however Golds does not specify the use of nitinol or radiopaque material. Chouinard teaches a stent-graft that utilizes nitinol (see col. 8, lines 22-28)

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and radiopaque material (21) see col. 7, lines 42-470. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the metal stent portion of Golds from nitinol because Golds states in section [0025] that the stent can be self-expandable and nitinol is a material widely used in the art vascular prosthesis art known for this properties. It also would have been obvious to one having ordinary skill in the art to provide a radiopaque material on *any* location of the device because it is well known that radiopaque material helps the surgeon to track the correct placement of the stent-graft.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Golds in view of Cook et al. 2004/0082989. Golds has been disclosed above however Golds does not specify that the film layer extends beyond the ends of the middle layer. Cook et al. teaches a stent graft wherein the ends of the graft material extend beyond the mesh layer (see figure 10 and section [0041]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to extend the film layer to any length beyond the mesh layers in order to help encase the mesh layers and/or to help protect the blood vessel from the ends of the mesh.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

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13. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read "Suzette J. Jackson", followed by a horizontal line.

Suzette J. Jackson
20 August 2004